IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP. Plaintiff, v. ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC. (formerly known as SULZER ORTHOPEDICS, INC.), Defendant.	Case No.: 05-CV -897-WHW-CLW *Document Electronically Filed* **ORAL ARGUMENT REQUESTED** **Motion Date: September 19, 2016**

DEFENDANT ZIMMER'S MOTION FOR FEES AND PREJUDGMENT INTEREST

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I. INTRODUCTION

This Court correctly observed that after 11 years, Howmedica's patents are "dead and buried." But having spent 11 years and $16+ million to get to this point, it is cold comfort to Zimmer to know it has finally "won." Zimmer asks this Court to declare this case "exceptional" and award Zimmer what it spent to prove these patents invalid.

Two publications – the Streicher reference and the Lue reference – rendered the patents at issue invalid. The United States Patent and Trademark Office ("PTO") initially refused to grant Howmedica's patents over the Streicher reference. To overcome that rejection, Howmedica withheld key invalidity tests, discarded bad data without informing the PTO, and refused to directly answer the PTO's questions. Howmedica also swore to the "General Rule," and along with its dishonest testing, overcame the PTO's rejection and obtained the patents in suit.

Once in litigation, Defendants produced the Lue reference, which clearly invalidated Howmedica's claims (as the Federal Circuit confirmed earlier this year). Howmedica began a course of flip-flopping that this Court noted (likening one of its presentations to the Keystone Cops), and found three of the four patents invalid, a decision the Federal Circuit confirmed.

Zimmer put the fourth patent back before the PTO in reexamination, in which Howmedica again withheld all evidence of its initial misconduct before the PTO and refused to allow Zimmer to submit it. It was only through monumental toil of this Court, the PTO and the Federal Circuit that these patents got the burial they deserved. And, that took place only after Zimmer spent a small fortune exposing Howmedica's fraud and misdirection. This risk of fighting these patents was enough to force defendant Smith & Nephew to settle with Howmedica just before the Federal Circuit took up the final appeal from the PTO's invalidation of Howmedica's last patent.

Zimmer understands it is asking this Court to once more wade into a complex factual record.[1] Unless it does, however, Howmedica will be rewarded for the duration and extent of its fraud, while Zimmer, which "won," will be $16 million poorer. This case is "exceptional" in every sense of the word, and is one in which this Court should compensate Zimmer for its losses in winning and to deter Howmedica from similar misconduct in the future.

II. PROCEDURAL HISTORY

The patents-in-suit—US Patents 6,174,934 (the "'934 patent"); 6,372,814 (the "'814 patent); 6,664,308 (the "'308 patent"); and 6,818,020 (the "'020 patent")—were the last four patents to issue in a family containing nine total patents and a later rejected patent application (the "'510 Application"). (Ex. 1-4) The last patent issued on November 16, 2004, and Howmedica sued Zimmer and Centerpulse Orthopedics ("Zimmer") and co-defendant Smith & Nephew on the patents soon thereafter. (Dkt. 1)

All four patents are invalid. On June 13, 2007, this Court held the '934, '814, and '308 patents invalid as indefinite for failing to properly define a critical claim limitation (the "Arrhenius claim limitation"). (Dkt. 176-177) After this Court rejected Howmedica's reconsideration motion (Dkt. 200-201), the Federal Circuit affirmed *per curiam*. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 397 F.App'x 654 (Fed. Cir. 2010).

A year later, in 2008, this Court held that Zimmer's accused products did not infringe claims 7-12 in the remaining '020 patent because those claims required heating ***below*** the melting temperature of ultra-high molecular weight polyethylene ("UHMWPE"), while Zimmer's products are heated ***above*** the melting temperature. (Dkt. 247-248)

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[1] This Court's task is made easier by Howmedica's having admitted several hundred facts underlying this motion in opposition to Zimmer's motion for summary judgment of inequitable conduct (a motion rendered moot due to the patents being found invalid). (Dkt. 264-2)

Zimmer requested *inter partes* reexamination of the '020 patent on January 22, 2009. The PTO granted that request and rejected all the '020 patent claims over prior art. (Ex. 5-6) The Patent Trial and Appeal Board ("PTAB") affirmed the examiner's rejection of claims 1-6, but reversed as to claims 7-12. (Ex. 7-8) Howmedica appealed claims 1-6 to the Federal Circuit, and Zimmer cross-appealed on claims 7-12. The Federal Circuit agreed with Zimmer, holding claims 1-6 are invalid as anticipated, and reinstating the rejection of claims 7-12 as obvious. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951 (Fed. Cir. 2016). This Court entered final judgment on July 27, 2016. (Dkt. 424).

III. FACTUAL BACKGROUND

Howmedica's patents disclose a process for irradiating and heat-treating medical implant materials. Because this process was known, Howmedica told the PTO that its ***particular*** time/temperature combination (heating at 50°C/144 hours) would achieve crosslinking ***not*** found in the prior art. Howmedica repeatedly lied to the PTO when it made these arguments.

A. Technology Background

Polyethylene is a long chain of repeating ethylene units classified based on the size of these chains, with those having molecular weights in the millions often classified as "UHMWPE." (Ex. 1, col 1:30-32) It is commonly irradiated to strengthen and/or sterilize it. (Ex. 9, p. 80) Radiation breaks bonds in the chains and creates "free radicals." (Ex. 10, p. 34-chart; Ex. 1, col. 1:57-58) In the presence of oxygen, some free radicals react with oxygen molecules and cause oxidation. (Ex. 10, p. 34-chart; Ex. 1, col. 2:37-40)

However, if the polyethylene is kept in an oxygen-free (or inert) atmosphere during and after irradiation, the free radicals will bond to one another and form additional crosslinks. (Ex. 10, p. 34-chart; Ex. 1, col. 2:55-60) As the material becomes increasingly crosslinked and fewer

free radicals are available to react with oxygen, the polyethylene is protected from oxidation, or stabilized. (Ex. 1, col. 2:60-64; Ex. 11, ¶10-18)

The crosslinking reaction occurs at all temperatures, but speeds up at higher temperatures. (Ex. 1, col. 6:53-55; Ex. 12, ¶15) The 100-year old Arrhenius equation describes the relationship between the temperature of a reaction and the time needed to complete the reaction to a particular level (Ex. 1, col. 6:55-65), stating that the rate at which a chemical reaction takes place rises exponentially with temperature. *Id*. Howmedica's expert admitted that "[o]ne of ordinary skill in the art further understands that, by applying the Arrhenius equation, a level of cross-linking in similarly irradiated UHMWPE materials may be obtained by utilizing various heating/annealing times and temperatures." (Ex. 13, ¶21)

Crosslinking of polyethylene is often measured by its solubility. (Ex. 14 at ZIM-0150522 "Gel Determinations"; Ex. 1, col. 10:47-50) Because crosslinked polyethylene is more difficult for solvents to dissolve (Ex. 15, ¶9), increased crosslinking increases the percentage of insoluble "gel," corresponding to a decrease in solubility (*i.e.*, % gel + % solubility = 100%). (Ex. 12, ¶21; Ex. 16, p. XV, Glossary, "Gel") Solubility is typically measured using the ASTM standard solvent xylene. (Ex. 14 at ZIM-0150522, "Gel Determinations")

B. During Prosecution Of The Patents-In-Suit, Howmedica Withheld Key Information And Data That Refuted Its Claim For Patentability

Many of the claims have limitations related to crosslinking as measured by solubility. (*E.g.* Ex. 1, col. 12, claims 5, 11; Ex. 4, col. 12, claims 1, 5, 7, 12) During prosecution of the '934 and '020 patents, the examiner rejected the solubility claims over prior art references Streicher and England. Howmedica submitted test evidence and argument to overcome those rejections, but withheld key evidence that proved the examiner was right to reject the claims.

1. Howmedica Withheld Key Solubility Testing Data Refuting The

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2. Howmedica Withheld Material Information That Altered The Conclusions To Be Drawn From Dr. Wang's Swell Ratio Data

Instead of submitting the directly applicable (and invalidating) solubility data, Howmedica had Dr. Wang calculate the swell ratio, which is an inverse measure of a material's level of cross linking—the lower the swell ratio, the higher the level of crosslinking. (Ex. 23, ¶3) Notably, unlike solubility, swell ratio testing is neither claimed nor mentioned in the patent. (Ex. 1, cols. 9:55-10:57) Howmedica misled the PTO here as well, in two ways.

[2] See "Gel Content" column. (*See also*, Ex. 20 for magnified data table) Gel contents above 99% mean less than 1% is soluble: % gel + % solubility = 100%. (Ex. 12, ¶21)

Withheld Swell Ratio Test. First, Dr. Wang submitted tests he said proved the Streicher material to have lower crosslinking than the patented material ("Application Method D Material" in the chart), based on the average of two samples of each:

Swell Ratio Data

DEC 17 1999

Material GUR1050 Irradiated in Nitrogen at 25 KGy (2.5 Mrad) and Tested Under ASTM D2765-90

	Average Swell Ratio (Average of Two Samples)
Application Method D Material	3.785
Streicher Method (annealed at 80°C for 2 hours in nitrogen)	4.08

(Ex. 23, ¶¶ 2-6 and chart (highlighting added); Ex. 24, p. 7)

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Withheld Statistical Information. Second, even as to the rigged swell ratio data (which is all the examiner had), the examiner was skeptical, saying "it is not clear whether the difference in average swell ratio is a significant improvement (3.785 compared to 4.08)." (Ex. 25, p. 3) In response, Dr. Wang submitted a declaration on statistical significance. (Ex. 26, ¶6) However,

[3] Dr. Wang admitted that "Duration I" is the same as the "Method D" material described in the patent, and that Howmedica claims as its invention. (Ex. 22, p. 218:11-12; Ex. 1, col. 8:9-15)

instead of comparing the swell ratios the examiner asked about (3.785 and 4.08), Howmedica instead said that Streicher's swell ratio was not statistically different from an ***entirely different prior art sample*** (nitrogen irradiated UHMWPE); he did not answer whether Streicher was statistically different than the patent. *Id*. The examiner allowed the claims based on Dr. Wang's declarations, and Howmedica used the same argument to obtain the '814 patent. (Ex. 27, p. 5, Ex. 28, p. 2) In explaining her allowance of the claims, the examiner stated: "[t]he [Wang] Affidavit submitted 05-04-2001 by Applicant provides evidence to show that the product obtained by the method taught by Streicher has a significantly different level of crosslinking as measured by swell ratio than the instantly claimed device." (Ex. 28, p. 2)

While Dr. Wang did not answer the examiner's question, he ***knew*** the answer. Dr. Wang's data proved that there was ***no statistical differenc***e between the 3.785 and 4.08 swell ratios that he had submitted. (Ex. 29, ¶50-56) The PTO could not determine this on its own because Howmedica only provided only the average swell ratios, not the individual data points needed to conduct a statistical analysis. (Ex. 21, at "N2 Only," "Duration," "R.S. Material") Howmedica's intent to conceal the information was made clear during the '020 patent reexamination, where Howmedica ***again*** failed to give this information (along with other key information) to the PTO, and refused Zimmer's request to allow Zimmer to submit it even after Zimmer explained its clear significance. (Ex. 30, *see* June 30, 2009 Letter at #1)

3. Howmedica Withheld Key Solubility Testing Data Published By The Inventors And Dr. Wang During '020 Prosecution

In prosecuting the '020 patent, Howmedica submitted claims requiring solubility (and dependent claims requiring the solvent be trichlorobenzene). (Ex. 31, claims 1, 8, 15, 17) The examiner rejected them over U.S. Patent 5,466,530 to England ("England"). (Ex. 32, p. 3) England discloses irradiation of UHMWPE in air with no post-irradiation heating, and the

examiner stated that "[England] would be expected to inherently have a solubility in some solvent of less than 80.9%, in a selected solvent, or in TCB [trichlorobenzene], as set forth in instant claim 8, in the absence of evidence to the contrary." *Id*.

In response, Howmedica argued that England did not disclose the claimed solubility level. (Ex. 33, p. 5) Dr. Wang testified that England disclosed material equivalent to the patent's Method B ("air irradiated," a prior art method). (Ex. 34, ¶5) According to Dr. Wang, the "solubility of the Method B material in trichlorobenzene (TCB) as shown in Table 3, is greater than 98.2%," and that "[c]onsequently, the England et al. material…would not be sufficiently crosslinked to have a solubility in TCB below 80.9% as claimed." *Id*. Relying on that argument, the PTO issued the '020 patent. (Ex. 35, p. 2)

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The PTO found these papers material during reexamination finding that "[t]here is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not claims 1 and 5 were patentable." (Ex. 5, p. 5) The examiner maintained her rejection throughout reexamination. (*E.g.*, Ex. 58, p. 5-6, 35-36)

4. Howmedica And Dr. Wang Failed To Disclose Dr. Wang's Affiliation With The Applicant At The Time Of His Declarations

As shown, Dr. Wang had a critical role in obtaining these patents, submitting several declarations to the PTO to overcome the examiner's rejections. But the PTO never knew that Dr.

Wang worked for Stryker, reported to and collaborated with the inventors, and coauthored papers about highly crosslinked UHMWPE with the inventors. When Dr. Wang submitted his

this information. (Ex. 41, p. 304:23-306:25) Applicants also withheld from the PTO the Wang papers that contradicted his affidavit. (Ex. 37-39).

C. When Confronted With The Lue Prior Art Reference, Howmedica Asserted A Claim Construction It Knew To Be False

A critical issue in this case was the meaning of "temperature and time at least equivalent to 50°C for 144 hours as defined by the Arrhenius' equation," found in all asserted claims of three of the asserted patents. When prosecuting the '934 patent, Howmedica originally claimed an irradiation and heat-treatment process that only required the material to be heated "at or above 25°C." (*e.g.*, Ex. 42, claim 1) The PTO rejected these claims in light of Streicher's disclosure of irradiation and heating at 80°C for 2 hours. (Ex. 18, p. 2-3)

To overcome Streicher, Howmedica added the limitation that the material be heated at a "temperature and time at least equivalent to 50°C for 144 hours as defined by the Arrhenius' equation." (*e.g.*, Ex. 1, col. 12, claim 1) Howmedica also submitted a declaration from Dr. Wang and argued that the limitation did not require actual use of the Arrhenius equation, but could be satisfied by applying a "General Rule." (Ex. 23, ¶7, Ex. 24, p. 8) According to Dr. Wang, the General Rule was that for every 10°C increase in temperature, the time required for the heating

process is reduced by half—heating at the claimed time/temperature combination of 50°C/144 hours will produce a material with equivalent properties as heating at 60°C for 72 hours, 70°C for 36 hours, 80°C for 18 hours, etc. Dr. Wang argued that because the General Rule predicted an equivalent material would be achieved by heating at 80°C for 18 hours, Streicher's disclosure of 80°C for 2 hours would result in an inferior material. (Ex. 24, p. 8) Along with Dr. Wang's withheld and misleading testing, this General Rule argument overcame the examiner's Streicher rejection. Howmedica's unsupportable actions during litigation regarding the General Rule are likewise central to its misconduct in this case.

1. Howmedica Initially Relied On The General Rule During Claim Construction

During claim construction in this case, Howmedica proposed that this Court replace the Arrhenius claim limitation with the General Rule. (Dkt. 46, p. 30) It argued, "For irradiated UHMWPE material, the general rule for 'equivalent' heating to the Arrhenius equation is that for every 10°C the heating temperature is increased, the time required to form a sufficient amount of crosslinks is cut in half." *Id*. Howmedica submitted sworn testimony from its expert, Dr. Li:

> One of ordinary skill in the art understands that, according to the Arrhenius equation and assuming first order kinetics, in order to achieve at least the same or similar level of cross-linking of free radicals in similarly irradiated UHMWPE, for every 10°C the heating temperature is increased, the heating time is cut in half. Similarly, for every 10°C the heating temperature is decreased, the heating time is doubled.

(Dkt. 46-9, ¶21) Howmedica's 30(b)(6) witness Aaron Essner testified likewise, that "[t]he Arrhenius equation to my knowledge is typically defined with a rule of thumb . . . ." (Ex. 43, p. 82:15-83:16), and that "[t]he rule of thumb is for every increase of ten degrees centigrade the time halves." (Ex. 43, p. 106:4-15)

2. Discovery of The Prior Art Lue Reference

After claim construction briefing but before this Court ruled, Defendants discovered the Lue reference, which discloses the claimed inert irradiation/post-irradiation heating process at a time/temperature combination of 150°C for 1 hour. (Ex. 16, p. 56) Under the General Rule, heating at 150°C would require less than 9 minutes to achieve crosslinking equivalent to the patents' 50°C for 144 hours.[4] Zimmer provided Howmedica an invalidity claim chart showing how Lue anticipated the patents, using the General Rule in the same exact way that Howmedica had done during prosecution and was urging this Court adopt as a claim construction. (Ex. 44) Howmedica could no longer continue the litigation in good faith; its appropriate course of action was to dismiss the case. But it did not, and it would be ten years before the PTO and Federal Circuit would confirm that Lue invalidated the claimed invention. (Ex. 7, p. 22); *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951, 959-60, 962-63 (Fed. Cir. 2016).

3. Howmedica Disavowed Its General Rule Construction

Instead, Howmedica "revised" its claim construction brief, disavowing the "General Rule" and arguing it was only a "guesstimate" that had previously been offered as a mere "aid" to the jury. (Dkt. 74-1, p. 1-2, Dkt. 74, p. 30) These characterizations contradicted what Howmedica said during prosecution, through its 30(b)(6) designee, through the sworn testimony of its expert Dr. Li, and in the briefs it submitted to this Court. *See supra.*

4. Howmedica's Inability To Provide Infringement Contentions

Howmedica's abandonment of the General Rule made its infringement contentions (which relied on the General Rule) inoperative, and created an indefiniteness problem—the patents did not provide enough information to actually use the Arrhenius equation. (Dkt. 176, p.

[4] Increasing the temperature ten degrees (50º→60º→ …→140°→150°) requires halving the time (144 hours→72 hours→…→17 minutes→8.5 minutes).

6-7) Defendants spent weeks seeking new infringement contentions; Howmedica stalled because it had no legitimate contentions to offer. (Dkt. 89-1, p. 15; Ex. 45-46) Defendants therefore moved for summary judgment of noninfringement based on Howmedica's failure to provide infringement contentions, or alternatively for indefiniteness. (Dkt. 89-1) The time was ripe—again—for Howmedica to voluntarily end the case. But it did not.

5. Howmedica Concocted An Alternative Construction Of The Arrhenius Claim Limitation That Fundamentally Contradicted The Patent Specification And Prosecution History

Instead, Howmedica invented a theory this Court would later liken to the Keystone Cops, arguing that Arrhenius could be applied with two time/temperature combinations that achieved equivalent crosslinking. (Dkt. 99, p. 17-19) Howmedica submitted ***another*** declaration from Dr. Li, who had previously advanced the General Rule. (Ex. 47)

Howmedica's new construction was baseless. The patents do not contain equivalent time/temperatures, and this Court correctly found that Howmedica's "evidence" was based on a single passage from the specification that "is ambiguous, is irrelevant to post-irradiation heating, and even contradicts Howmedica's expert position." (Dkt. 176, p. 17). After noting the hypocrisy of using Dr. Li to support the contradictory claim constructions, this Court invalidated the first three patents (Dkt. 176), a decision the Federal Circuit affirmed. *Howmedica Osteonics Corp. v. Zimmer, Inc.*, Appeal No. 2010-1162, 397 F. App'x 654 (Fed. Cir. 2010).

6. Howmedica Knew Its New Arrhenius Theory Was Contradicted By Dr. Wang's Testing Data Submitted During Prosecution

Howmedica did not simply lose a claim construction argument; it advanced a position that contradicted the very testing data it sent to the PTO to get the patents in the first place. As noted above, Howmedica and Dr. Wang submitted swell ratio testing to compare the level of crosslinking at the time/temperature combinations disclosed in the patent (50°C/144 h), the

Streicher reference (80°C/2 h), and that the General Rule predicts is equivalent to the patent (80°C/18 h). (Ex. 23, chart) Dr. Wang's testing actually showed that 80°C/18 h produced a lower swell ratio (more crosslinking) than 50°C/144 h, causing him to declare to the PTO that only ***15-18 hours of heating would be necessary at 80°C*** to achieve equivalent heating to the patent's heating of 50°C/144 hours. (Ex. 23, ¶3)

But Howmedica's new Arrhenius theory required heating for ***31 hours at 80°C***. (Dkt. 99-2, Risen Decl. at ¶26). Howmedica asserted this theory before this Court, the Federal Circuit, and the PTO despite knowing it was in direct contradiction to Dr. Wang's empirical testing data relied upon in prosecution to avoid the Streicher reference rejection.

D. Howmedica And Its Experts Regularly Switched Positions, Needlessly Extending Litigation

As shown above, Howmedica and its experts reversed course on sworn positions regarding claim construction and the General Rule. But they did more; whenever Howmedica's initial position proved unhelpful, its experts would simply change course notwithstanding their prior sworn testimony and submissions.

1. Howmedica's Experts Drs. Li And Pruitt Changed Positions On The Wang Papers

The '020 patent claims that recite a solubility limitation (claims 1, 5, 7, 12) specify that the solubility is less than 80.9% in trichlorobenzene. (Ex. 4) As described in section II.B.3, one of the Wang papers discloses the solubility of a material in "both trichlorobenzene and xylene," supporting a correlation between the two solubilities. (Ex. 39 at HOW066652, "Gel Content Measurement") Defendant's expert used the Wang papers to show how the prior art disclosure of solubility in xylene proves the solubility limitation was met. (*e.g.*, Ex. 48 at p. 26, 44)

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During reexamination of the '020 patent, the examiner rejected claims 1 and 5 of the '020 patent based on the solubility of the air irradiated material shown in the Wang papers. (Ex. 6, p. 5-6) Howmedica and Dr. Li advanced their "supplemental" position that the Wang papers reported solubility only in xylene to the PTO to try to get around the Wang papers. (Ex. 55, p. 14-15; Ex. 56, p. 13-15) Of course, Howmedica withheld Dr. Li's and Dr. Pruitt's ***initial*** opinions from the PTO, and refused to allow Zimmer submit them. (Ex. 30, June 30, 2009 Letter at #6-7) Zimmer warned Howmedica that it was unethical to withhold evidence of its experts' prior, contrary opinions, but Howmedica never submitted them to the PTO. (Ex. 30, June 30, 2009 Letter at #6-7)

2. Howmedica Had Dr. Streicher And Dr. Li Attempt To Directly Contradict The Streicher Prior Art Reference

The Streicher reference is core to this case, and Howmedica's efforts to get around it are central to this motion. During reexamination of the '020 patent in 2009, the examiner rejected

claims 1-6 over Streicher. (Ex. 6, p. 4-5) By that time, Dr. Streicher worked for Howmedica. (Ex. 57, ¶5-8) To try to overcome the examiner's rejection, Howmedica submitted a declaration from Dr. Streicher attempting to denigrate the teachings of his own earlier work. (Ex. 57) Drs. Streicher and Li swore that the Streicher reference material exhibited "substantial increases in oxidation" and "heavy oxidation." (Ex. 57, ¶22, 26-27) Dr. Streicher went so far as to state: "It is my understanding that a person of ordinary skill in the art reading my Streicher article prior to the '020 patented invention would not have used or pursued annealing UHMWPE after irradiation because it failed to eliminate or appreciably reduce oxidation, wear, or degradation." (Ex. 57, ¶23) These statements were intended to prove that the Streicher material was "bad," which would help Howmedica in the reexamination.

But the Streicher article expressly states the material had "enhanced crosslinking" and "negligible" oxidation. (Ex. 10, p. 43 left column, p. 39 left column) It also stated that "[a]nnealing as well as storage in nitrogen atmosphere . . . after radiation reduces postoxidation effects significantly" and "is beneficial for UHMWPE used as a biomaterial for endoprostheses and is therefore recommended for long term implants." (Ex. 10, p. 43, last two paragraphs) The examiner rejected both declarations, finding that "both the argument presented and the opinions expressed in the Streicher and Li declarations, are in direct opposition to the actual content of the Streicher article used in the rejection." (Ex. 58, p. 34-35)

E. Howmedica Asserted Arguments It Knew To Be False In The Prosecution Of Earlier Patents In This Family

Howmedica withheld key information from the PTO going back to the earliest applications in the family that infected the rest of the patent's in this family. US Patent 5,543,471 is an early divisional patent in the same family of patents as the patents-in-suit, and

has substantially similar claims as the patents-in-suit. During prosecution, the inventor, Dr. Sun, declared to the PTO:

> That based upon the ESR results, a free radical concentration of less than 1 x 10^{17}/g is achieved with the invention. Free radical concentrations are several orders of magnitude higher without the process taught in the application, i.e., irradiation in air or

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the PTO regarding the novelty of its claimed free radical level, violating their duty of candor, even while Dr. Sun acknowledged in his declaration that he was aware such false statements can jeopardize the validity of the application. (Ex. 59, ¶6) Howmedica refused to submit this key information to the PTO a second time during reexamination of the '020 patent (which contains claims with the exact same claim limitation), even after Zimmer asked that it be submitted. (Ex. 30, June 30, 2009 Letter at #8)

F. During This Case, Howmedica Tried To Withhold Key Evidence Showing Zimmer Did Not Infringe And Took Conflicting Positions In Litigation And Ongoing Prosecution

Before filing suit, Howmedica tested the properties of Defendants' accused products, including their solubility, levels of free radicals, and oxidation index. Zimmer sought these tests in discovery. (Ex. 61, at #6) But instead of making a complete disclosure, Howmedica produced

favorable test results, but withheld the unfavorable results. (Dkt. 148-1, at p. 6 and Appendix A; Dkts. 124, 126, 127) Howmedica produced the unfavorable results only on the eve of an *in camera* review ordered by then-Magistrate Judge Hedges. (Dkt. 127). Some of the withheld

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But at the same time, Howmedica was also prosecuting a continuation application of the '020 patent before the PTO (the "'510 Application") with claims containing the same oxidation index limitation as in the '020 patent. The examiner rejected those claims over the Streicher reference. Howmedica submitted oxidation index testing by its employee Shi-Shen Yau (the same employee who coordinated the above testing of Defendants' products) showing that Streicher had an oxidation increase of 0.02, which Dr. Yau claimed to the PTO was a "***significant increase*** [ ] in oxidation index." (Ex. 64, Yau, p. 3-4) The examiner relied on Dr. Yau's testimony in issuing an initial Notice of Allowance of those claims. (Ex. 65, p. 2)

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for the accused products was ***"insignificant"*** and within the "nonincreasing" limitation to try to avoid a finding of noninfringement, while at the same time and through the work of the same employee, argued to the PTO that an oxidation index increase of .02 for the Streicher prior art was ***"significant."*** Howmedica did not inform the PTO of these contradictory positions.

IV. THE STANDARD GOVERNING EXCEPTIONAL CASES

Reasonable attorney's fees may be granted to a prevailing party in exceptional cases "to prevent an alleged infringer from suffering a gross injustice." 35 U.S.C. § 285; *Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1313 (Fed. Cir. 2013) "[Section] 285 is remedial and for the purpose of compensating the prevailing party for the costs it incurred in the prosecution or defense of a case where it would be grossly unjust . . . to require it to bear its own costs." *Id.* The need "to advance considerations of compensation and deterrence" is relevant. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 n. 6 (2014).

An exceptional case "is simply one that stands out from others with respect to the substantive strength of the party's litigating position (considering both the governing law and the facts of the case) ***or*** the unreasonable manner in which the case was litigated." *Octane Fitness,* 134 S. Ct. at 1756 (emphasis added). Courts consider the "totality of the circumstances" when determining whether a case is exceptional, including "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." *Id.* at 1756, 1756 n. 6; *see also SFA Sys., LLC v. Newegg, Inc.*, 793 F.3d 1344, 1348 (Fed. Cir. 2015). No single element is dispositive, and can include "bad faith litigation, objectively unreasonable positions, inequitable conduct before the PTO, [and] litigation misconduct." *Stragent, LLC v. Intel Corp.*, No. 6:11-cv-421, 2014 WL 6756304, at *3 (E.D. Tex. Aug. 6, 2014) (Dyk, J.).

V. THIS COURT SHOULD DECLARE THIS CASE EXCEPTIONAL

A. Inequitable Conduct Gives Rise To Exceptional Case

"[P]revailing on a claim of inequitable conduct often makes a case 'exceptional,' leading potentially to an award of attorneys' fees under 35 U.S.C. § 285." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc); *Intellect Wireless, Inc. v.*

Sharp Corp., 45 F. Supp. 3d 839, 851 (N.D. Ill 2014) ("Plaintiff likely would not have obtained the patents at issue nor sued the Defendants here for infringement" had it not committed inequitable conduct). To prove inequitable conduct, Zimmer must show that: (1) but for the deceptive conduct, the PTO would not have allowed a claim; and (2) "the patentee acted with specific intent to deceive the PTO." *Therasense*, 649 F.3d at 1290-91.[5]

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This Court can find this case exceptional without making a finding of inequitable conduct by clear and convincing evidence. Judge Bryson of the Federal Circuit, sitting by designation, recently ruled that "inequitable conduct is neither a necessary nor sufficient condition for a finding of exceptionality." *DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, No. 2-12-cv-00764, 2015 WL 1284669, at *5 (E.D. Tex. Mar. 20, 2015); *see also Strechline Intellectual Props. LTD. v. H&M Hennes & Mauritz LP*, No. 2:10-cv-371, 2015 WL 5175196, at *5-6 (E.D. Va. Sept. 3, 2015); *E. Coast Sheet Metal Fabricating Corp. v. Autodesk, Inc.*, No. 12-cv-517, 2015 WL 4603463, at *5 (D.N.H. July 30, 2015).

[6] Inequitable conduct committed during prosecution of the '934 patent renders the other patents-in-suit unenforceable under the doctrine of infectious unenforceability. *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006)

Supp. 2d 1297, 1326-27 (S.D. Fla. 2013) *aff'd* 763 F.3d 1354 (Fed. Cir. 2014) (failure to disclose test results contradicting representations about prior art the basis of rejection). This Court need not guess as to the materiality of the Wang papers because the PTO already found them material, finding the Wang papers proved the England reference disclosed the claimed solubility limitation and, therefore, rejecting the patent's claims. (*e.g.*, Ex. 58, p. 5-6, 35-36)

b. Failure To Disclose Contradictory Swell Test Results

c. Failure To Disclose Dr. Wang's Employment

Howmedica's misrepresentation of Dr. Wang as disinterested was material to patentability. (Section III.B.4) A declarant's relationships with the patent applicant are material when the relationship was significant and the declarant's views on the underlying issues are material. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187-88 (Fed. Cir. 2006); *Apotex*, 970 F. Supp. 2d at 1325 (failure to disclose financial interest creates presumption that the expert is disinterested and independent; PTO cannot examine this issue); *Caron v. QuicKutz, Inc.*, No. CV-09-02600, 2012 WL 5497869, at *10 (D. Ariz. Nov. 13, 2012) ("[g]iven the ex parte nature of proceedings before the PTO, it is especially important that the examiner has all the information needed to determine whether and to what extent he should rely on declarations presented by the applicant").

The examiner relied on Dr. Wang's representations that the patented material have more crosslinking than the Streicher material, as shown by examiner's statement in the notice of allowance of the '814 patent, in which she stated "[t]he Affidavit submitted 05-04-2001 by Applicant provides evidence to show that the product obtained by the method taught by Streicher has a significantly different level of crosslinking as measured by swell ratio than the instantly claimed device." (Ex. 28, p. 2) The examiner was entitled to know that Dr. Wang was employed by Stryker's subsidiary,[7] had reported to inventor Casper Stark for eight years while the patents were being obtained, and that he had coauthored several papers with the named inventors that discussed material being patented. *See eSpeed, Inc. v. Brokertec USA, L.L.C.*, 480 F.3d 1129, 1136 (Fed. Cir. 2007) (failure to disclose possible bias material omission where declarations submitted to overcome prior art).

2. Affirmatively Egregious Misconduct

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Dr. Wang's misrepresentations to the PTO are material for the independent reason that in cases involving "affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, materiality is presumed." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1346 (Fed. Cir. 2013). Such misconduct is material per se because "a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent." *Therasense*, 649 F.3d at 1292. Such misconduct may also give rise to an inference of intent to deceive, because of "the affirmative acts of submitting [false affidavits], their misleading character, and the inability of the examiner to investigate the facts." *eSpeed*, 480 F.3d at 1138. Dr. Wang's failure to disclose the solubility test data that contradicted his conclusions about the prior art, and his longstanding relationships with the patentee and named inventors, including coauthoring papers relating to the subject matter of the patents, were all affirmative egregious misconduct. Doing so created the impression that he was a disinterested expert. This was not true. *See Apotex*, 970 F. Supp. 2d at 1328-29 (failure to disclose contradictory test results and failure to disclose longstanding association with patentee was affirmative egregious misconduct).

Dr. Sun's false affidavit misrepresenting the scope of the prior art is also affirmative egregious misconduct. (Section III.E) Any misconduct done during the prosecution of the '471 patent applies to the patents-in-suit. *See Mosaid Techs. Inc. v. Samsung Elecs. Co., Ltd.*, 362 F. Supp. 2d 526, 553-54 (D.N.J. 2005) (infectious unenforceability requires that related patents are unenforceable due to inequitable conduct when they bear an immediate and necessary relation to the inequitable conduct).

3. Howmedica Acted With Deceptive Intent

Applicant and Dr. Wang intended to deceive the PTO by submitting Dr. Wang's declarations. "Because direct evidence of deceptive intent is rare," a court may infer intent from

indirect and circumstantial evidence, provided that the inference is the "single most reasonable inference" available and that the evidence is sufficient to require a finding of deceitful intent "*in light of all the circumstances*." *Therasense*, 649 F.3d at 1290 (emphasis added). "Partial disclosure of material information about the prior art to the PTO cannot absolve a patentee of intent if the disclosure is intentionally selective." *Am. Calcar, Inc. v. Am. Honda Motor Co.,*

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Streicher material was well within the claimed levels. (Ex. 22, 225:3-17); *see also Therasense*, 649 F.3d at 1290 (deliberate decision to withhold known material information shows intent). Howmedica's decision to withhold papers authored by the inventors and its declarant that contained tests of the claimed material and the prior art is more proof of its intent to deceive the PTO. (Section III.B.3)

Dr. Wang's use of an average of two ***favorable*** swell test data points to overcome a rejection, combined with his omission of the contradictory data point, also supports a finding of intent. (Section III.B.2) *See Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1367 (Fed. Cir. 2007) (finding intent where examiner relied on improved property of oil to allow claims and patentee withheld test results showing that prior art may have had the same property; omitted data at heart of question before the examiner); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1570 (Fed. Cir. 1983) ("[i]t cannot be disputed that the purpose of the affidavits was to overcome prior-art rejections that had been entered by the examiner."). Dr. Wang's response

when the examiner asked whether the difference between the claimed method and Streicher was significant further evidences Howmedica's intent to deceive. Dr. Wang did not answer the examiner's question, but instead obfuscated and stated that the difference ***between Streicher and another prior art material*** was "not statistically different." This ignored the question of whether the claimed method was better than Streicher. Dr. Wang knew that it was not.

Dr. Wang's and Mr. Augustin's failure to disclose Dr. Wang's affiliation with the patentee and the named inventors further support a finding of intent to deceive. (Section III.B.4) Dr. Wang and Mr. Augustin were aware of Dr. Wang's employment with Stryker, that he had reported to inventor Stark, and that he was involved with the prosecution of the patent applications, and failed to disclose this information. *See Caron*, 2012 WL 5497869, at * 11 (specific intent to deceive inferred from failure to disclose declarants' financial relationship with patentee and misrepresenting qualifications of other declarants). Howmedica's multiple false statements and repeated material omissions support a finding that a specific intent to deceive is the single most reasonable inference here. *See Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1235 (Fed. Cir. 2007) (affirming inequitable conduct where issues collectively "indicated repeated attempts to avoid playing fair and square with the patent system"); *see also Ohio Willow Wood*, 735 F.3d at 1351 (vacating summary judgment of no inequitable conduct; patentee's withholding of various pieces of material information and multiple misrepresentations would support finding that intent was single most reasonable inference). Thus, Howmedica's multiple intentional omissions and false statements constituted inequitable conduct.

B. Howmedica Also Engaged In Litigation Misconduct

"[A] wide variety of proofs can provide the requisite showing of bad faith under § 285." *Kilopass*, 738 F.3d at 1314. "[A] case can be found exceptional when a party prolongs litigation in bad faith." *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1328 (Fed. Cir. 2013).

"[A] party . . . must continually assess the soundness of pending infringement claims, especially after an adverse claim construction." *Id.* "When a plaintiff is notified of the defects of its case yet continues to assert its claims in light of overwhelming evidence to the contrary, and proceeds with arguments that a reasonable attorney would know are baseless, it litigates in bad faith." *Astrazeneca AB v. Dr. Reddy's Labs., Ltd.*, No. 07-civ-6790, 2010 WL 1375176, at *4-7 (S.D.N.Y. Mar. 30, 2010); *see also Lugus IP, LLC v. Volvo Car Corp.*, No. 12-cv-2906, 2015 WL 1399175, at *4-6 (D.N.J. Mar. 26, 2015). Howmedica repeatedly prolonged litigation by taking blatantly contradictory positions to preserve the validity of its patents and its infringement arguments against Zimmer.

1. Howmedica Failed To Withdraw Claims It Knew Were Baseless And Advanced Unreasonable Litigation Positions

Howmedica's failure to dismiss this case when the Lue reference was disclosed ten years ago, just a year into this case, shows its subjective bad faith. Howmedica knew in 2006 that the asserted patents were anticipated by the Lue reference. (Section III.C.2) Instead of dismissing the case, Howmedica unnecessarily prolonged the case by disavowing its initial Arrhenius claim construction position based on the General Rule argument it presented in prosecution. (Section III.C.3) Howmedica then opposed Defendants' subsequent summary judgment motion of noninfringement and invalidity by presenting an infringement theory that contradicted the patents' specifications. (Section III.C.5) This argument had no support in the patent and directly contradicted Howmedica's own test results. (Section III.C.5-6) This Court likened Howmedica's presentation, and specifically its expert's contradictory testimony, to an "Abbott and Costello skit" and invalidated three of the patents in suit. (Dkt. 176) But there was nothing funny about Howmedica's costly reversal—it would cost Zimmer an additional 4 years of litigation after Howmedica's initial Arrhenius claim construction flip-flop to bring an end to

those three patents and the baseless argument that Howmedica knew from the outset had been disproven by its own testing data years earlier. (Section III.C.6)

Howmedica's doubling down after it was clear that it did not have a case renders this case exceptional. *Source Search Techs., LLC v. Kayak Software Corp.*, No. 11-cv-3388, 2016 WL 1259961, at *5-7 (D.N.J. Mar. 31, 2016) (case exceptional because "this flip-flopping stands out from the others with respect to the substantive strength of a party's litigating position").

2. Howmedica Constantly Took Contradictory Positions Throughout Litigation

Howmedica's experts took diametrically opposed viewpoints throughout this case in a whatever-it-takes effort to extend the life of clearly invalid patents. Dr. Li submitted two opposing declarations in support of Howmedica's flip-flop on the construction of the Arrhenius claim term, causing this Court to note "Dr. Li's current testimony contradicts his rule of thumb."

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declaration in an effort to dismiss the value of his prior work disclosed in the Streicher reference, causing the PTO to find his statements in "direct opposition to the actual content of the Streicher article." (Section III.C.6)

Howmedica's opposing positions weren't confined to validity. Where "the patentee is manifestly unreasonable in assessing infringement, while continuing to assert infringement in court, an inference is proper of bad faith, whether grounded in or denominated wrongful intent, recklessness, or gross negligence." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990); *see also Raylon, LLC v. Complus Data Innovations, Inc.*, 700 F.3d 1361, 1368-

70 (Fed. Cir. 2012) (vacating denial of fees award; patentee asserted claim constructions "so

that an oxidation index of 0.02 was "significant" to avoid anticipation by Streicher. (Section III.D.2) Howmedica never informed the PTO of Dr. Li's flip-flop. *Id*.

C. Howmedica Withheld Material Information During Reexamination With An Intent To Deceive The Patent Office

Howmedica's conduct during reexamination overwhelmingly supports a finding that this case is exceptional. Conduct during reexamination can support a finding of subjective bad faith. *Novartis Corp. v. Webvention Holdings LLC*, No. CCB-11-3620, 2015 WL 6669158, at *5 (D. Md. Oct. 28, 2015) (patentee's failure to disclose prior art to PTO during reexamination until after the merits phase of the reexamination had concluded supported an inference of subjective bad faith). Howmedica's continuing failure to disclose Dr. Wang's test results even after Zimmer had filed an inequitable conduct motion in this Court based on those results, its refusal to allow Zimmer to submit the test results, and its subsequent attacks on Zimmer's expert's testing of Lue shows its bad faith during litigation. Howmedica also submitted expert declarations that, as the Examiner found, directly contradicted the prior art before the PTO.

VI. THE COURT SHOULD EXERCISE ITS DISCRETION TO AWARD ATTORNEYS' FEES HERE BECAUSE THE CASE IS EXCEPTIONAL AND ZIMMER'S ATTORNEYS' FEES AND COSTS ARE REASONABLE

Once the Court finds a case is "exceptional," it must then exercise its discretion to determine whether to award fees. *Kilopass*, 738 F.3d at 1317. Courts do so where "the interest of justice warrants fee-shifting," *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1582 (Fed. Cir. 1992), because "it would be *grossly unjust* that the winner be left to bear

the burden of his own counsel." *J.P. Stevens Co. v. Lex Tex Ltd.*, 822 F.2d 1047, 1052 (Fed. Cir. 1987) (emphasis in original). An award of attorneys' fees is appropriate here because Zimmer had to spend eleven years to invalidate patents that should never have issued and only issued because of Howmedica's fraud upon the PTO and, despite the outcome being clear a year into the case, had to continue litigating for another decade.

VII. FEES & EXPENSES SOUGHT

The amount of attorneys' fees awarded depends on the extent to which the case is exceptional. *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1344 (Fed. Cir. 2001). Given the amount of time over which Howmedica perpetuated its fraud of a lawsuit against Zimmer, and Zimmer's total victory, Zimmer deserves full compensation in this case.

In addition, consideration should be given to the fact that already in 2006, Howmedica was claiming almost $2 ***Billion*** in damages (Ex. 66, p. 7), a claim certain to multiply when extended through patent expiration in 2013. Zimmer was fully justified in seeking counsel suitable for such a case of this size, and in charging them with defending the case vigorously.

ATTORNEYS' FEES: In the Third Circuit, attorneys' fees are calculated using the "lodestar" approach, which requires multiplying the amount of time reasonably expended by reasonable hourly rates. *Lugus IP*, 2015 WL 1399175 at *6. The party seeking fees bears the initial burden of proving the reasonableness of the time and hourly rates used is in the lodestar calculation, and once proven, the adverse party bears the burden of challenging the reasonableness of the requested fees. *Id*. The declaration of Bryan Hales provides a breakdown of the various fees billed and paid by Zimmer, attorney time spent on this matter, and hourly rates for each attorney for which recovery is sought. (Ex. 68, ¶24) As shown by the declaration from Valeo Partners, which specializes in collecting and analyzing billing rates in the legal

industry, the attorney rates billed to Zimmer are in line with those of comparable firms. (Ex. 68 at Ex. E. at ¶8-13) Zimmer seeks **$13,496,086.96** in attorney and staff fees. (Ex. 68, ¶25)

EXPENSES: A fees award under 35 U.S.C. §285 includes "those sums that the prevailing party incurs in the preparation for and performance of legal services related to the suit." *Central Soya Co., Inc. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1578 (Fed. Cir. 1983); s*ee also, Vehicle Interface Techs., LLC v. Jaguar Land Rover N. Am., LLC*, No. 12-cv-1285, 2016 WL 3436396, at *5 (D. Del. June 15, 2016) (allowing expenses relating to "travel, food, lodging, mail, photocopying, facsimile, courier, filing fees, deposition transcripts, subpoena services, and other related services"). The Hales declaration itemizes the specific expenses sought by Zimmer, totaling **$513,258.38**. (Ex. 68, ¶26)

EXPERTS: This court has the "inherent authority to impose sanctions in the form of reasonable expert fees in excess of what is provided for by statute." *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 921 (Fed. Cir. 2012). This authority is usually applied in cases of "fraud or bad faith." *Id*. (citing *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 378 (Fed. Cir. 1994)). To ignore Howmedica's continual deceit and lack of candor before multiple tribunals in this case, would condone a calculated fraud upon both this Court and the PTO. Howmedica repeatedly committed fraud on the PTO throughout the prosecution of the patents in this patent family: from inventor Dr. Sun's dishonest statements regarding the novelty of the free radical levels in the patent, to Dr. Wang's repeated withholding of key data and misdirection regarding the results of the data he did submit. Howmedica's bad faith continued during litigation, as evidenced by its Hail Mary reversal on claim construction to avoid the clearly anticipatory Lue reference. This bad faith persisted throughout the case: Howmedica repeatedly took claim construction and infringement positions that contradicted its own previous arguments,

and refused to permit Zimmer to disclose Howmedica's own inconsistent test results to the PTO during reexamination. Because Howmedica's experts were part and parcel to Howmedica's deceit, Zimmer had to call upon its experts to debunk and reveal Howmedica's deceit, at great expense. Zimmer seeks recovery of **$1,016,599.29** in expert fees, of which all but roughly $13,000 was incurred after Howmedica's claim construction reversal to avoid the clearly anticipatory Lue reference. (Ex. 68, ¶27)

PREJUDGMENT INTEREST: When fees are awarded under §285, a Court may also exercise its inherent equitable power to award prejudgment interest in instances of "bad faith and other exceptional circumstances." *Mathis v. Spears*, 857 F.2d 749, 761 (Fed. Cir. 1988). Courts have used either the prime rate or T-Bill rate, but regularly find that using the prime rate of interest best "represents the cost of borrowing money, which is a 'better measure of of the harm suffered as a result of the loss of the use of money over time.'" *Church & Dwight Co., Inc. v. Abbott Labs.*, No. 05-cv-2142, 2009 WL 2230941, at *10 (D.N.J. July 23, 2009); *see also U.S. Phillips Corp. v. Iwasaki Elec. Co.*, 607 F.Supp. 2d 470, 483 (S.D.N.Y 2009); *NTP, Inc. v. Research In Motion, Ltd.*, 270 F. Supp. 2d 751, 763 (E.D. Va. 2003). Zimmer believes that given the extreme length of time over which Howmedica perpetuated bad faith arguments in this litigation, an amount derived from the prime rate of interest is warranted—**$5,821,225.69**. (Ex. 67 at III.2).

VIII. CONCLUSION

For all of the above reasons, Zimmer respectfully requests this Court award it just compensation under 35 U.S.C. §285 and the Court's inherent equitable powers.

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Respectfully submitted,

/s/ Brian M. English

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